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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,112	11/20/2003	Johannes Bartholomaus	785-011574-US(PAR)	8885

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

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07/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,112	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-8,27-29 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-8,27-29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/29/07 has been entered.

Claims 1,2,4,6-8,27-29 and 31 are pending in the application. Claims 3,5,9-26,30 and 32-40 have been cancelled in the amendment filed 5/29/07.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1,2,4,6-8,27-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what "quantities" of component C are required to provide a dosage form with a breaking strength of at least 500N. The specification does not clearly define the quantity of component C necessary for such a property.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1,2,4,6-8,27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1) in view of Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) and Maggi et al. (Biomaterials **2002**, *23*, 1113-1119).

5. Oshlack et al. (US 2003/0064099A1) discloses a controlled release (p2, [0026]) oral dosage form of an opioid analgesic (p4, [0056]) with reduced abuse potential due to the addition of an aversive agent/gelling agent, such as polyethylene oxide (p4, [0049]) which reduces the absorption of the opioid analgesic through injection when the dosage form is tampered with (p2, [0021-0023]). Polyalkylene oxide molecular weights vary from 1,000,000 to 10,000,000 (p13, [0151]). The dosage form may be a sustained release form in a matrix prepared via melt-extrusion techniques (p9, [0111]). The sustained release matrix form involves directly metering into an extruder a hydrophobic sustained release material, such as polylactic-acid-polyethylene oxide copolymers (p6, [0073]), the opioid analgesic, one or more aversive agents, such as polyethylene oxide, etc. (p7, [0080]; p10, [0113-0114]). Suitable controlled release tablets may be formulated from multiparticulate formulations, wet granulation that is compressed into a tablet or melt and may contain hydrophobic binders, such as carnauba wax (p7, [0081];

p8, [0099]; p9, [0110-0111]; p10, [0120]). Oshlack et al. does not explicitly disclose the a dosage form having a breaking strength of at least 500N.

6. Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) discloses the preparation of stabilized sustained release tablets prepared by hot-melt extrusion and the stability of polyethylene oxide (PEO) polymers of molecular weight 1,000,000 and 7,000,000 in the matrix tablet prepared by hot-melt extrusion (p242, paragraphs 4 and 5; p249, paragraph 1). The final product may take the form of granule and formed into tablets (p242, paragraphs 2 and 7; p243, paragraph 6).

7. Maggi et al. (Biomaterials **2002**, *23*, 1113-1119) discloses the use of high molecular weight polyethylene oxides (PEOs) in controlled release matrices and the measurement of crushing/breaking strength and dissolution of the tablets (p1113, paragraph 1). The evaluation of tablets containing PEOs of different molecular weights was studied, such as tablets consisting of diltiazem, excipients and PEOs (p1114, paragraph 3). The preparation of the tablets involved compression at compression forces of 10 and 30kN and heating from 30°C to 130°C, whereas the melting temperatures of the tablets are about 70°C (p1114, paragraph 8; figure 1). The application of certain compression force levels on the polymer affects the solid state (morphology) of the polymer (crystalline or amorphous) (p1114, paragraph 10). The crushing strength, which is recorded in table 2 (p1115), and dissolution of the tablets was measured (p1114, paragraph 11 and 12; p1115, paragraph 4) and the swelling/erosion characteristics of the tablets were examined via image analyzer and the different morphological phases (of the polymers) appear as well-defined areas of

contrast (p1115, paragraph 3). The release profiles (i.e. controlled) for the tablets are not only controlled by the drug solubility, but also the physical and mechanical properties of the gel forming polymer layer of the tablet (p1114, paragraph 1). The crushing strength is directly correlated to the compression force applied to press the tablet and also to the molecular weight of the PEOs. The compression force seems to have no influence on the dissolution behavior of the matrices (p1115, paragraph 8). The controlled release matrices generate a gel layer at the matrix surface upon exposure to water (p1113, paragraph 1).

It is respectfully pointed out that instant claim 29 is a product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

8. At the time of invention it would have been obvious to one ordinarily skilled in the art to generate an abuse-proofed dosage form as disclosed by Oshlack et al. via melt extrusion technique (Oshlack et al. and Zhang et al.). The advantages of the hot-melt extrusion technique over traditional techniques includes fewer processing steps, the elimination of time-consuming drying steps and avoids the problems with uniformity and segregation during the tableting process (Zhang et al. p242, paragraph 1; p249, paragraph 1). It is also obvious that the breaking strengths of the tablets of the

combined disclosures are controlled by the polymer characteristics (i.e. molecular weight, morphology) as disclosed by Maggi et al. Increasing the compression force increases crushing strength so it would be obvious to one skilled in the art to apply different compression forces during the preparation of the tablets to generate those of the desired breaking strength. The sustained release dosage forms of Oshlack et al. encompass those of the instant claims and the breaking strength and tablet characteristics and can be manipulated as disclosed by Maggie et al. with a great expectation of success to produce tablets capable of having a breaking strength of at least 500N.

9. Claims 1,2,4,6-8,27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 6,733,783B2) in view of Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) and Maggi et al. (Biomaterials **2002**, *23*, 1113-1119).

10. Oshlack et al. (US 6,733,783B2) discloses a bioavailable controlled-release hydrocodone formulation/tablet (column 1; column 6, line 61-66) that includes carauba waxes (column 8, line 30), additional drugs, and polyethylene oxide polymer (column 17, lines 38-41) with molecular weights that encompass those of the instant claims. The method of preparing the formulation/tablets includes melt-extrusion (column 9, lines 53-55; column 10, lines 18-22). The processes may be used in combination and the extrudate can be cut, shaped, molded, compressed and spheronized (column 11, lines 9-22). Oshlack et al. does not explicitly disclose the a dosage form having a breaking strength of at least 500N.

11. Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) discloses the preparation of stabilized sustained release tablets prepared by hot-melt extrusion and the stability of polyethylene oxide (PEO) polymers of molecular weight 1,000,000 and 7,000,000 in the matrix tablet prepared by hot-melt extrusion (p242, paragraphs 4 and 5; p249, paragraph 1). The final product may take the form of granule and formed into tablets (p242, paragraphs 2 and 7; p243, paragraph 6).

12. Maggi et al. (Biomaterials **2002**, *23*, 1113-1119) discloses the use of high molecular weight polyethylene oxides (PEOs) in controlled release matrices and the measurement of crushing/breaking strength and dissolution of the tablets as well as that stated above.

It is respectfully pointed out that instant claim 29 is a product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

13. At the time of invention it would have been obvious to one ordinarily skilled in the art to generate an abuse-proofed dosage as disclosed by Oshlack et al. which is drawn to the preparation of tablets via melt extrusion technique. The advantages of the hot-melt extrusion technique over traditional techniques includes fewer processing steps, the elimination of time-consuming drying steps and avoids the problems with uniformity

and segregation during the tableting process (Zhang et al. p242, paragraph 1; p249, paragraph 1). It is also obvious that the breaking strengths of the tablets of the combined disclosures are controlled by the polymer characteristics (i.e. molecular weight, morphology) as disclosed by Maggi et al. Increasing the compression force increases crushing strength so it would be obvious to one skilled in the art to apply different compression forces during the preparation of the tablets to generate those of the desired breaking strength. The sustained release dosage forms of Oshlack et al. encompass those of the instant claims and the breaking strength and tablet characteristics and can be manipulated as disclosed by Maggie et al. with a great expectation of success to produce tablets capable of having a breaking strength of at least 500N.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1,2,4,6-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11,19,25-27 and 36 of copending Application No. 10/567,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredients, excipients, etc. of the abuse-proofed dosage form, such as opioid drug, polymer and wax of the copending application 10/567,594 encompass those of the instant claims. The tablets of the instant claims and copending application 10/567,594 are in the form of controlled release tablet which are prepared in the same manner (i.e. melt). The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The tablets of copending application 10/567,594 are thermoformed by extrusion without discoloration which is encompasses by the thermoformed dosage of the instant claims which does not exclude extruded forms without discoloration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1,2,4,6-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11,19,25-27 and 30 of copending Application No. 11/349,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

ingredients, excipients, etc. of the abuse-proofed dosage form, such as opioid drug, polymer and wax of the copending application 11/349,537 encompass those of the instant claims. The tablets of the instant claims and copending application 11/349,537 are in the form of controlled release tablet which are prepared in the same manner (i.e. melt). The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The instant claims may be formed with or without extrusion and therefore encompasses those of copending application 11/349,537 which are thermoformed without extrusion. The instant claims do not exclude preparation of the thermoformed dosage without extrusion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1,2,4,6-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 21 of copending Application No. 10/890,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredients, such as opioid drug, polymer and waxes of the copending application 10/890,707 encompass those of the instant claims. For instance the (1R,2R)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)phenol agent of the copending application 10/890,707 anticipates the opiate of the instant claims and the controlled release tablets of the instant claims encompass the delayed release tablets of copending application 10/890,707. The polymer characteristics of both tablet formulations, such as molecular weight are

identical, therefore allowing for the same breaking strength. The dosage form of copending application 10/890,707 does not exclude thermoformed dosage forms.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1,2,4,6-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 22 of copending Application No. 10/890,763. Although the conflicting claims are not identical, they are not patentably distinct from each other because the abuse-proof dosage form of copending application 10/890,763 encompasses that of the instant claims whereas the ingredients, such as opioid drug, polymer and waxes are equivalent. For instance the (1R,2R)-3-(2-dimethylaminomenthyl-cyclohexyl)phenol agent of the copending application 10/890,763 anticipates the opiate of the instant claims and the controlled release tablets of the instant claims encompass the delayed release tablets of copending application 10/890,763. The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The dosage form of copending application 10/890,763 does not exclude thermoformed dosage forms.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1,2,4,6-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 14-16 of copending Application No. 11/462,216. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredients, excipients, etc. of the abuse-proofed dosage form, such as opioid drug, polymer and wax of the copending application 11/462,216 encompass those of the instant claims. The tablets of the instant claims and copending application 11/462,216 are in the form of controlled release tablet which are prepared in the same manner (i.e. melt). The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The tablets of copending application 11/462,216 are thermoformed by extrusion without discoloration which is encompasses by the thermoformed dosage of the instant claims which does not exclude extruded forms without discoloration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
July 3, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER